

applying this reference the Examiner states that Davis discloses an instrument for forming a bore comprising a handle (an unshown chuck attached to 22), a rod 12 and a means 34 for engaging cortical bone. Figure 2 of the Davis reference is referred to with respect to Claim 2.

Claim 3 stands rejected under 35 U.S.C. 103 as being unpatentable over the Davis patent in view of Patent 5,122,134 -- Borzone, et al. The Examiner relies on the latter as disclosing semi-elliptical fins for efficient cutting. He concludes that it would have been obvious at the time of applicant's invention to make the fins of Davis semi-elliptical, in view of Borzone et al., to cause the cutting to be more efficient.

The Examiner notes that Patents 5,013,318 - Spranza and 5,171,248 - Ellis disclose indicia on rods with fins. The following additional references are cited as disclosing centering devices:

Patent 4,337,773 - Raftopoulos et al.
Patent 5,108,405 - Mikhail et al.
Patent 5,470,336 - Ling et al.

Reconsideration and withdrawal of the rejections of the remaining Claims 1-5, 7 and 8 are requested based on the amendments made to the main Claim 1 and the comments which now will be presented.

A full understanding of applicant's invention requires an appreciation of the problems facing a surgeon in placing a

properly sized prosthesis at a correct location within a femoral canal.

Although it is possible prior to surgery to ascertain approximate dimensions of a femoral canal by X-ray techniques, or more exact dimensions by expensive CAT scan procedures, the utility of such preoperative analyses is affected by the surgery itself, because at the time of the surgery, the reference for relevant measurements becomes the location where the surgeon cuts the femoral head to obtain access to the femoral canal. Thus, it is desirable that as the surgery occurs, the surgeon have available instruments for forming and measuring a bore in the femoral canal.

The shape of the femoral canal contributes to the problem facing the surgeon. The canal is not cylindrical. In the region of its proximal end the canal has a wider dimension, medial to lateral, than the anterior to posterior dimension. However, at about 6 inches from its proximal end, the canal changes shape such that the medial-lateral dimension is narrower than the anterior-posterior dimension.

Applicant's invention is one which permits the surgeon to take measurements during the surgical procedure while simultaneously creating a centered bore in the femoral canal. This is accomplished by an instrument having fixed to its distal ends outwardly projecting elements lying in a plane such that

when the instrument is inserted into the canal to a depth where the elements engage the interior wall of cortical bone which defines the canal, the bore is centered and the width of the canal at that depth is known because of the span of the projecting elements. By orienting the plane of the projecting elements in the medial-lateral plane of the femoral canal, or in the canal's anterior-exterior plane, and by using instruments having different spans, the dimensions of the canal can be determined at any depth. This allows the surgeon to select a prosthesis having a properly sized femoral stem. This is most important, for if the stem is oversized, the potential for bone breakage exists. On the other hand, an undersized stem is subject to loosening during use. Also, because the bore formed by the instrument in the oval-shaped canal is centered, the stem of the prosthesis is properly oriented when it is introduced into the canal.

The main Claim 1 now has been amended to more specifically set forth applicant's invention. More particularly, the claim now calls for the instrument to include a rod having means fixed at its distal end, and projecting outwardly from opposite sides of the rod in a plane, for engaging the wall of the intramedullary canal and centering the rod relative to the wall. None of the references relied on by the Examiner discloses or suggests such an arrangement.

The patent to Davis cited as being anticipatory of the invention originally set forth in Claims 1, 2 and 4-8 clearly is not relevant to the instrument now claimed. Davis discloses a reaming head 18 mounted on the distal end of a rotatable shank 12. In operation, Davis' device merely drills a bore in bone. Obviously, the rotating head 18 does not serve to center the reamer within cancellous bone. It simply cuts away anything in its path to form a bore defined by the way the reamer is directed.

The Borzone et al. patent does not overcome the deficiencies of Davis as a reference with respect to the structure recited in amended main Claim 1. Borzone et al. disclose another type of reamer in which a cutting head 14 is connected to a drill shaft 16 to ream a bore in bone. Shaft 16 is flexible, but its direction of movement in a medullary canal is established by a guide shaft 52 positioned within an existing bore formed in the canal. The head 14 enlarges the bore as it is moved along the canal.

From the discussion of Davis and Borzone et al. just presented, it is apparent that whether taken singly or in combination, they neither disclose nor suggest the invention now recited in amended Claim 1 and the dependent Claims 2-5, 7 and 8.

Although not specifically relied on to reject the claims, the secondary references will be discussed briefly.

The patent to Ellis describes a medullary caliper quite different in structure from applicant's claimed instrument. Ellis discloses a mechanical arrangement in which a rod 28 slides within a sleeve 12 to cause a pair of caliper arms 32 and 34 to deflect outwardly to measure the width of a canal within bone. By contrast, applicant's claimed instrument has no moving parts and is characterized by elements which are fixed to the distal end of a rod in planar relationship and which project outwardly therefrom in opposite directions to engage an interior wall which defines an intramedullary canal in a femur. Thus, applicant's device has utility both in measuring the width of the canal and centuring the bore formed in the canal.

The Spranza device is not capable of measuring the width of a canal in bone. Its sole intended use is to measure the depth of holes in bone so that fasteners of correct length can be selected by a surgeon.

Raftopoulos et al. relates to a device for inserting a plug near the bottom of a cavity formed in a femoral canal. The patent neither discloses nor suggests the formation of a centered bore in the canal or an instrument to measure the canal's width at different depths of the canal.

The remaining patents to Mikhail et al. and Ling et al. pertain to prostheses revision surgery wherein a bore already has been formed in the femoral canal. Consequently, it is believed

JOHNSON, L.

Ser. No. 08/389,399

that these patents have no relevancy to applicant's invention as now claimed.

For the reasons presented, it is urged that the present amendment overcomes the formal deficiencies and rejections presented in the February 28, 1996 paper. Consequently it is believed that the application now is in condition for allowance and such action is solicited.

Respectfully submitted

CUSHMAN DARBY & CUSHMAN

By 

Kevin E. Joyce

Reg. No. 20,508

Tel. No.: (202) 861-3050

Fax No.: (202) 822-0944

KEJ:jl

1100 New York, Avenue, N.W.
Ninth Floor
Washington, D.C. 20005-3918
(202) 861-3000